PSY9
A NETWORK META-ANALYSIS OF RANDOMIZED, CONTROLLED TRIALS OF USTEKINUMAB AND ADALIMUMAB FOR MODERATE-TO-SEVERE PSORIASIS

Odom D[1], Brogan A[1], Talbird SE[1], Schenkel B[2]
[1]RTI Health Solutions, Research Triangle Park, NC, USA, [2]Janssen Scientific Affairs, LLC, Horsham, PA, USA

OBJECTIVES: Psoriasis is a chronic, immune-mediated, inflammatory skin disease that negatively impacts patients' health-related quality-of-life. Biologic medications have been developed and approved for the condition in recent years that have greatly improved patients' care; however, little is known about their comparative efficacy. Our research objective was to synthesize and compare the efficacy of two of these new biologic treatments, ustekinumab and adalimumab. **METHODS:** A literature review was conducted of randomized, controlled trials investigating the efficacy of ustekinumab (45 mg or 90 mg) and adalimumab (40mg) according to their approved FDA labels. As no head-to-head trials existed at the time of the study, a Bayesian network meta-analysis allowing for indirect comparisons was conducted on the ordered probit scale to evaluate comparative efficacy at a common week-12 time point based on the Psoriasis Area and Severity Index (PASI) 50, 75, 90, and 100 and the Physician's Global Assessment (PGA) 0/1. The primary analysis was based on the intent-to-treat populations, and sensitivity analysis was conducted using the ustekinumab dose appropriate for patients' body weight per the product label. **RESULTS:** Seven clinical trials representing over 4,000 patients were included in the meta-analysis. The meta-analysis showed that PASI 50, 75, 90, and 100 response rates at week 12 were 76%, 55%, 29%, and 10% for adalimumab; 89%, 73%, 47%, and 20% for ustekinumab 45 mg; and 91%, 76%, 51%, and 24% for ustekinumab 90 mg, respectively. PGA 0/1 response rates at week 12 were 58%, 64%, and 69% for adalimumab, ustekinumab 45 mg, and ustekinumab 90 mg, respectively. Weight-based sensitivity analysis showed similar results between adalimumab and ustekinumab but higher efficacy for ustekinumab 45 mg in pts ≤100kg compared with ustekinumab 90 mg in pts >100kg per the label. **CONCLUSIONS:** This network meta-analysis provides additional information about the comparative effectiveness of ustekinumab and adalimumab in treatment of moderate-to-severe PsO.

PSY10
TREATMENT OF PERIPHERAL NEUROPATHIC PAIN WITH THE CAPSAICIN 8% PATCH: AN OBSERVATIONAL, REAL-WORLD STUDY IN SIX EUROPEAN COUNTRIES

Poole CD[1], Chambers C[2], Odeyemi II[2], Currie CJ[1]
[1]Cardiff University, Cardiff, UK, [2]Astellas Pharma Europe Ltd., Chertsey, UK

OBJECTIVES: The capsaicin 8% patch (QUTENZA™) is licensed for the treatment of peripheral neuropathic pain in non-diabetic adults. The purpose of this observational study was to determine if levels of effectiveness observed in clinical trials are translated into routine clinical practice, and to determine how this novel treatment is being used more generally by practicing physicians so that real-world cost effectiveness can be determined. **METHODS:** This observational study of routine practice (ASCEND) is being carried out using an online, electronic data capture platform for the case report forms that includes translation into multiple languages. Following treatment, at least 12 months' follow-up is planned for each patient in this ongoing study. Demographic, clinical, process and patient-reported outcome parameters are reported. Pain is evaluated using the Numeric Pain Rating Scale (NPRS). **RESULTS:** A total of 166 patients from 31 hospital sites in six European countries have been enrolled and treated with capsaicin 8% patch. Of these 59% are female with an overall mean age of 58.7 (sd 14.5) years. The reported indications include post-operative and/or post-traumatic neuropathic pain (n 67; 43.2%) and post-herpetic neuralgia (31; 20.0%). Baseline mean pain score was 6.57 (sd 1.98) units. Pain improved by an average of 1.8 and 2.3 units on the NPRS at weeks two and eight, respectively (paired samples comparison p<0.001 at both time points). A total of 56% of enumerable subjects (N=100) were classified as responders to treatment (≥30% improvement in pain at the Week 8 assessment). On average, 1.5 (sem 0.06) patches were used per treatment. **CONCLUSIONS:** When used in routine clinical practice, the degree of pain relief evident when using the capsaicin 8% patch was greater than the levels seen in randomised trials. Interestingly, this was achieved with a reduced number of patches, suggesting current cost-effectiveness estimates based on clinical trial data may be conservative.

PSY12
META-ANALYSIS OF RANDOMIZED CLINICAL TRIALS OF THYROIDECTOMY WITH ULTRASONIC SCALPAL VERSUS CONVENTIONAL SURGERY

Li H[1], Xu D[2]
[1]China Pharmaceutical University, Nanjing, Jiangsu, China, [2]Johnson & Johnson Medical China, Beijing, China

OBJECTIVES: Undertake a meta-analysis of all randomized controlled trials (performed in China and other Countries) comparing effective and safety of ultrasonic scalpel (UAS) with conventional surgery for thyroidectomy. **METHODS:** A comprehensive search for published RCTs published in major medical database (PubMed, Embase, Elsevier, Wanfang and CNKI) was performed from January 2003 to November 2012; Reviews of each study were conducted and data were extracted.Outcome measures analyzed included operation time, intraoperative blood loss, overall drainage volume, length of stay and post-operative complication rates. **RESULTS:** Data were retrieved from 26 RCTs(16 from China, 10 from other countries) describing 3011 patients In most cases conventional vessel ligation and tight were used as a conventional method. The results of the meta-analysis demonstrated significant improvement of perioperative outcomes with the use of UAS instead of conventional surgical instrumentation. Operative time was significantly reduced from a mean of 84.6 min to 61.7(WMD: -21.66 minutes; 95% CI: -22.61, -20.71) intraoperative blood loss was decreased from a mean of 61.4 ml to 31.6 ml (WMD: -23.58 mL; 95% CI: -24.33,-22.83),length of stay was shorten from a mean of 5.8 to 4.8 days (WMD: -0.8 day; 95% CI: -0.86, -0.72) , overall drainage volume was reduced from a mean of 56.9 ml to 37.4(WMD: -21.28 mL; 95% CI: -22.15, -20.41) in the patients underwent thyroidectomy with UAS. It also showed that the patients who were treated with UAS presented more favorable results in incidence of post-operative complications (OR: 0.54, 95% CI: 0.36, 0.81). **CONCLUSIONS:** Ultrasonic scalpel showed significant advantages over conventional methods in the thyroidectomy, including shortened operation time, shortened length of stay, reduced intraoperative blood loss and shortened overall drainage volume. Besides, it can also decrease the post-operative complication risks.

PSY13
EFFECTS OF PHENTERMINE AND TOPIRAMATE EXTENDED-RELEASE (PHEN/TPM ER) TREATMENT ON WEIGHT LOSS (WL) WHEN STRATIFIED BY BASELINE BODY MASS INDEX (BMI) OVER 1 YEAR

Ryan D[1], Church T[2], Karnawat S[3], Troupin B[3]
[1]Pennington Biomedical Research Center, Baton Rouge, LA, USA, [2]Biomedical Research Center, Baton Rouge, LA, USA, [3]VIVUS, Inc., Mountain View, CA, USA

OBJECTIVES: The 1998 NHLBI Obesity Guidelines state "extremely obese persons often do not benefit from more conservative treatments for WL." This *post-hoc* analysis explores the use of PHEN/TPM ER, a pharmacologic adjunct to lifestyle modifications, to impact WL across BMI ranges, including extreme obesity. **METHODS:** Data from two double-blind, placebo-controlled Phase 3 studies (CONQUER [BMI ≥27 to ≤45kg/m^2], EQUIP [BMI ≥35kg/m^2]) were pooled and subjects stratified by baseline BMI (kg/m^2; <30, ≥30-<35, ≥35-<40, ≥40-<45, ≥45) and by randomized dose over 56 weeks (ITT-LOCF). Subjects were randomized to placebo (n=1477), PHEN 3.75mg/TPM ER 23mg (3.75/23; n=234), PHEN 7.5mg/TPM ER 46mg (7.5/46; n=488), or PHEN 15mg/TPM ER 92mg (15/92; n=1479). All subjects received the same lifestyle intervention. **RESULTS:** At baseline, mean weight was 107.4 kg and mean BMI was 38.4 kg/m^2. At week 56, least-squares mean percent WL was -1.5%, -4.7%, -8.2%, and -10.4% for placebo, 3.75/23, 7.5/46, and 15/92, respectively (P<.0001 versus placebo). Similar dose trends were seen when subjects were stratified by baseline BMI for placebo, 3.75/23, 7.5/46, and 15/92, respectively: BMI <30, -1.1%, dose not included in CONQUER, -9.1%, and -9.1%; BMI ≥30-<35, -1.8%, -10.3%, -8.0%, and -10.4%; BMI ≥35-<40, -1.8%, -5.5%, -8.8%, and -10.2%; BMI ≥40-<45, -1.9%, -4.4%, -8.3%, and -11.5%; and BMI ≥45, -1.3%, -5.5%, -8.8%, and -11.0% (P<0.005 versus placebo, all comparisons with 7.5/46 and 15/92). Similar WL trends were observed with mean absolute WL (P<0.005 versus placebo, all comparisons with 7.5/46 and 15/92). Common adverse events were constipation, dry mouth, and paraesthesia. **CONCLUSIONS:** PHEN/TPM ER was associated with significant WL versus placebo across all BMI categories, with dose proportional percent WL increases across BMI categories within each treatment arm. We conclude that significant WL is possible across a wide range of BMIs, including extreme obesity, with PHEN/TPM ER use.

PSY14
OBSERVATIONAL STUDY OF FERRIC CARBOXYMALTOSE (FCM) IN FRANCE (ONCOFER STUDY; INTERIM ANALYSIS)

Toledano A[1], Luporsi E[2], Morere JF[3], Scotté F[4], Huot-Marchand P[5], Zakin L[6], Mahi L[7], Bugat R[8]
[1]American hospital of Paris, neuilly sur seine, France, [2]Centre Alexis Vautrin, Vandoeuvre Les Nancy , Meurthe et Mosel, France, [3]Hôpital Avicenne, Bobigny, France, [4]Hôpital Européen George Pompidou, Paris, Ile de France, France, [5]ICTA, fontaine les dijon, France, [6]Vifor Pharma International, Neuilly-sur-Seine Cedex, Ile de France, France, [7]Vifor Pharma International, Neuilly-sur-Seine Cedex, France, [8]Institut Claudius Regaud, Toulouse, France

OBJECTIVES: This French multicenter observational study aims to describe clinical practice Ferric carboxymaltose (FCM) use in patients with hematological malignancies or solid tumors. **METHODS:** Two cohorts of patients (1:1) are enrolled. Cohort 1 (retrospective): patients treated in 2010 with any intravenous iron (IV) or red blood cell transfusion if no IV iron; Cohort 2 (prospective): patients treated with FCM after July 1st 2011. Patient characteristics were collected for a period of 3 months pre and post intervention. Outcomes of the first 100 patients are described below. **RESULTS:** Fifty patients were analyzed in each cohort (mean age, 62 and 66 y.; solid tumors, 84% and 100%; metastatic, 61% and 63% for Cohorts 1 and 2, respectively). In Cohort 1, 16 patients received intravenous iron (iron sucrose (IS)) and 34 were transfused. The mean total iron dose was 706 mg for IS in cohort 1 and 960 mg for FCM in cohort 2; the mean number of infusions was 3.8 and 1.8 for IS and FCM respectively. In cohort 2, 69% of the administrations were done at home. In patients receiving FCM without erythropoietin stimulating agents (ESA), mean Hb (g/dL) increased from 10.9 to 12.1, from baseline to Month 3. ESA use was 44% in cohort 1 vs 22% in cohort 2 during observational period. No serious adverse events related to IS or FCM were observed. **CONCLUSIONS:** FCM was well tolerated and effective in treating iron deficiency anemia. FCM was mostly given at home with fewer infusions required compared to IS. Interim results to be confirmed by the final analysis.

PSY15
META-ANALYSIS FOR EFFICACY OF ROMIPLOSTIM FOR TREATMENT OF IMMUNE IDIOPATHIC THROMBOCYTOPENIA

Aggarwal S, Topaloglu H, Messenger M
Novel Health Strategies, Bethesda, MD, USA

OBJECTIVES: Immune (idiopathic) thrombocytopenia (ITP) is an autoimmune condition characterized by increased platelet destruction and suboptimal